UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

JENNIFER REYNOLDS-SITZER and KENNETH SITZER,

*Plaintiffs*,

v. No. 1:21-cv-0145

EISAI, INC. and ARENA PHARMACEUTICALS, INC.,

*Defendants*.

- - - - - - - - - - - - - - - - - - - - - - - - - - - - - - - -

APPEARANCES: OF COUNSEL:

DOUGLAS & LONDON, P.C. VIRGINIA E. ANELLO, ESQ.
*Attorneys for Plaintiffs*
59 Maiden Lane, 6th Fl.
New York, New York 10038

BOND, SCHOENECK & KING, PLLC JONATHAN B. FELLOWS, ESQ.
*Attorneys for Defendant EISAI, Inc.*
One Lincoln Center
Syracuse, New York 13202

SIDLEY AUSTIN LLP ALAN E. ROTHMAN, ESQ.
*Attorneys for Defendant Arena Pharmaceuticals, Inc.*
787 Seventh Avenue
New York, New York 10019

DAVID N. HURD
United States District Judge

**MEMORANDUM-DECISION and ORDER**

## I. INTRODUCTION

Plaintiffs Jennifer Reynolds-Sitzer ("Jennifer") and Kenneth Sitzer ("Kenneth" and, together with Jennifer, "plaintiffs") bring this products liability action against defendants EISAI, Inc. ("EISAI") and Arena Pharmaceuticals, Inc. ("Arena" and, together with EISAI, "defendants"). Plaintiffs assert claims under various legal theories related to Jennifer's use of the prescription medicine Belviq.

Defendants move pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(6) and 9(b) for partial dismissal of plaintiffs' complaint. The motions having been fully briefed, the Court will now consider them on the basis of the parties' submissions without oral argument.

## II. BACKGROUND

### A. Belviq

EISAI, along with its parent company, and Arena, along with its wholly-owned subsidiary, were responsible for developing the pharmaceutical drug Belviq.[1] Dkt. 1 ("Compl.") ¶ 4. Belviq, also known as lorcaserin hydrochloride, is a first-in-class oral selective serotonin 5HT2c receptor agonist drug approved by the U.S. Food and Drug Administration ("FDA") in

[1] The facts are taken from the complaint, because for the purposes of a motion to dismiss under Rule 12(b)(6) or 9(b), the Court must "accept as true the factual allegations of the complaint, and draw all inferences in favor of the pleader." *Rosner v. Bank of China*, 349 F. App'x 637, 638 (2d Cir. 2009).

2012 to be used as an adjunct to diet and exercise for weight management in adults. *Id.* ¶¶ 2, 39, 40, 47, 55.

Before ultimately receiving FDA approval for Belviq, defendants conducted a two-year carcinogenicity study in rats that revealed an increase in certain tumors, Compl. ¶¶ 56-59, and a study done in mice that had similar findings, *id.* ¶¶ 60-61.

In January 2020, the FDA issued a safety communication regarding clinical trial results that showed a possible increased risk of cancer associated with Belviq. Compl. ¶ 81. In this communication, the FDA stated that its evaluation of the potential risk was ongoing, and that it was uncertain of a causal association at that time. *Id.*

On February 13, 2020, the FDA announced that EISAI had submitted a request to voluntarily withdraw Belviq from the market because data from its Phase IV clinical trials indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration. Compl. ¶ 82. The FDA further stated that the risks of Belviq outweighed its benefits, recommended that patients stop taking Belviq and dispose of any unused pills, and instructed all health care professionals to both stop prescribing Belviq and to contact their patients taking the drug to inform them of their increased risk of cancer. *Id.*

Aside from its safety issues, plaintiffs also allege that Belviq was not effective as a weight-loss drug. *See, e.g.*, Compl. ¶¶ 4, 62-64, 70. Specifically, the combined data from clinical studies of Belviq revealed between 3.1-3.3% mean weight loss over that of the placebo groups, meaning that they failed to meet the mean efficacy criterion of FDA's obesity draft guidance. *Id.* ¶¶ 62-64, 70. Moreover, one two-year study of Belviq found that all treatment groups had experienced weight regain during their second year of taking the drug. *Id.* ¶ 62.

According to plaintiffs, despite knowing about these safety and efficacy risks, defendants warranted and represented that Belviq was safe and effective to use. Compl. ¶¶ 178-79.

**B. Jennifer Reynolds-Sitzer**

Jennifer learned of Belviq after seeing repeated television advertisements for the drug between 2015 and 2016. Compl. ¶¶ 184-86. As a result of these advertisements, plaintiff became interested in using Belviq, and she contacted her physician, Dr. Jason Kittler ("Dr. Kittler") to seek a prescription for the drug. *Id.* ¶¶ 187-88.

After meeting with Dr. Kittler and discussing Belviq's efficacy and side effects, which Dr. Kittler obtained by reviewing the drug's label, Jennifer began using Belviq in May 2016. Compl. ¶¶ 188-94. Sometime after she

started using Belviq, plaintiff developed thyroid cancer, which she alleges the drug caused. *See*, *e.g.*, *id.* ¶¶ 93-95, 216.

## III. LEGAL STANDARD

"To survive a Rule 12(b)(6) motion to dismiss, the 'factual allegations must be enough to raise a right to relief above the speculative level.'" *Ginsburg v. City of Ithaca*, 839 F. Supp. 2d 537, 540 (N.D.N.Y. 2012) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). Instead, the complaint must contain sufficient factual matter that it presents a claim to relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A claim is facially plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*

In assessing the plausibility of a complaint, it is "to be construed liberally, and all reasonable inferences must be drawn in the plaintiff's favor." *Ginsburg*, 839 F. Supp. 2d at 540. The complaint may be supported by "any written instrument attached to it as an exhibit, materials incorporated in it by reference, and documents that, although not incorporated by reference, are 'integral' to the complaint." *L-7 Designs, Inc. v. Old Navy, LLC*, 647 F.3d 419, 422 (2d Cir. 2011).

## IV. DISCUSSION

Applying New York law, there are four theories under which plaintiffs may pursue a recovery based upon a claim of products liability: (1) strict liability; (2) negligence; (3) express warranty; and (4) implied warranty. *Scism v. Ethicon, Inc.*, 2020 WL 1245349, at *3 (N.D.N.Y. Mar. 16, 2020) (citing *Oden v. Boston Sci. Corp.*, 330 F. Supp. 3d 877, 888 (E.D.N.Y. 2018)). Each theory requires the plaintiff to prove: (1) the product was defective in design or manufacture; and (2) the product was the actual and proximate cause of her injury. *Id.*

Plaintiffs bring claims under each of the above theories, as well as fraud-based claims and a claim for loss of consortium on behalf of Kenneth. Defendants have moved to dismiss the following counts of the complaint: (I) negligence; (II) strict liability – defective design and failure to warn; (III) breach of express warranty; (IV) breach of implied warranty; and (V) fraudulent misrepresentation and concealment.[2] The Court addresses each in turn.

### A. Negligence and Strict Liability

Under New York law, "[a] manufacturer who places into the stream of commerce a defective product which causes injury may be held strictly

[2] Defendants also moved to dismiss plaintiffs' sixth cause of action for negligent misrepresentation, but plaintiffs withdrew this claim with the filing of their opposition brief. *See* Dkt. 20 at 2.

liable." *Scism*, 2020 WL 1245349, at *3 (citing *McCarthy v. Olin Corp.*, 119 F.3d 148, 154 (2d Cir. 1997)). There are three distinct claims for strict products liability: (1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a design defect, which results when the product as designed is unreasonably dangerous for its intended use; and (3) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm. *McCarthy*, 119 F.3d at 154-55.

Defendants move to dismiss plaintiffs' design defect claim for failure to state a claim and plaintiffs' warning defect claims under the Learned Intermediary Doctrine. For the failure to warn claims, which plaintiffs bring under theories of negligence and strict liability, defendants only seek dismissal to the extent that plaintiffs allege defendants owed a duty to anyone other than Jennifer's physician. The Court disagrees with defendants and declines to dismiss these claims.

**1. Defective Design**

"A defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use[.]" *Scism*, 2020 WL 1245349, at *4 (citing *Oden*, 330 F. Supp. 3d at 888). In other words, the

product must be "one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Id.*

To adequately plead a design defect, a plaintiff must show: (1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury. *Scism*, 2020 WL 1245349, at *4 (citing *Oden*, 330 F. Supp. 3d at 888). As to the first element, a plaintiff must "identify a particular problem in the design" of the allegedly defective device to survive a motion to dismiss under Rule 12(b)(6). *Id.* However, failure to do so "does not necessarily defeat a design defect claim at the pleading stage" because plaintiffs "may not possess this sort of technical information without discovery and expert consultation." *Hunter v. Shanghai Huangzhou Elec. Appliance Mfg. Co.*, 505 F. Supp. 3d 137, 153 (N.D.N.Y. 2020) (citing *Parillo v. Stryker Corp.*, 2015 U.S. Dist. LEXIS 191834, at *12 (N.D.N.Y. Sep. 29, 2015)). Finally, a plaintiff must also "plead facts alleging the existence of a feasible alternative design." *Id.*

Defendants first argue that plaintiffs fail to adequately allege the existence of a feasible alternative design. Plaintiffs allege that Belviq, designed as a serotonin receptor agonist for weight loss, posed a substantial likelihood of harm, and that the safer alternative was a drug that did not affect the serotonin pathway. *See, e.g.*, Compl. ¶¶ 4, 146-48, 151, 160, 173.

This is sufficient to place defendants on notice of the nature of plaintiffs' claim; demanding any further detail would "require the plaintiff to possess technical or scientific knowledge about the inner workings of the product, which would contravene the notice pleading requirement of [Rule] 8, even under the *Iqbal–Twombly* standard." *See Sullivan v. Aventis, Inc.*, 2015 WL 4879112, at *7 (S.D.N.Y. Aug. 13, 2015) (citing *Williamson v. Stryker Corp.*, 2013 WL 3833081, at *4 (S.D.N.Y. July 23, 2013)).

Indeed, plaintiffs offer more detail than the plaintiff in *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601 (S.D.N.Y. 2012) – the only case defendants cite in support of their argument concerning a pharmaceutical drug.[3] In *DiBartolo*, the plaintiff did not allege the existence of a safer feasible alternative design at all and merely noted that the mode of action "[spoke] to the inherent defect" of the drug. *Id.* at 622 n.9. By contrast, plaintiffs in this case note that the safer alternative to Belviq was a drug that did not affect the serotonin pathway. Compl. ¶¶ 55, 146-48. While they do not allege a specific alternative medication to Belviq, plaintiffs explain why – defendants exclusively possess this information. *Id.* ¶ 103. Since Belviq is a "first in

[3] Defendants' other two principal cases, which involve medical devices, are likewise inapposite because the proposed alternative designs there varied greatly from the original product. *See Taylor v. Medtronic, Inc.*, 2020 U.S. Dist. LEXIS 30836, at *8 (N.D.N.Y. Feb. 24, 2020) (holding that surgical techniques not involving the use of hernia mesh at all were not feasible alternative); *Oden v. Boston Sci. Corp.*, 330 F. Supp. 3d 877 (E.D.N.Y. 2018) (holding replaceable filter design not a feasible alternative to a permanent filter). In this case, while the mode of action for plaintiffs' proposed alternative may vary from the original drug, both Belviq and plaintiffs' alleged alternative are pharmaceutical drugs designed to be taken over time for weight loss.

class" drug, it is plausible that defendants, as its designers, would be in the sole possession of any alternative designs. *See Fuller v. Eisai Inc.*, 2021 U.S. Dist. LEXIS 8184, at *10-14 (E.D. La. Jan. 15, 2021) ("Given that Belviq is a 'first-in-class' drug, the Court finds it plausible that any alternative design would be in the sole possession of the company that designed it").

Defendants' second argument for dismissal, that plaintiffs offer only a formulaic recitation of the elements of a design defect claim, also fails. In support of this argument, defendants cherry-pick just four of plaintiffs' allegations. Yet, as plaintiffs correctly note, a broader reading of the complaint reveals that it contains sufficient factual allegations for the Court to infer the existence of a design defect.

Contrary to defendants' assertions, plaintiffs sufficiently allege that Belviq posed a substantial likelihood of harm. Specifically, plaintiffs highlight defendants' own animal studies and clinical trials of Belviq indicating that the drug can cause cancer. *See, e.g.*, Compl. ¶¶ 56-59, 60-61, 62-74. Although plaintiffs do not allege a specific design defect, requiring them to do so in this instance would require technical or scientific knowledge, and go beyond Rule 8's notice pleading requirement. *See Sullivan*, 2015 WL 4879112, at *7; *Hunter*, 505 F. Supp. 3d at 153; *Parillo*, 2015 U.S. Dist. LEXIS 191834, at *12. In any event, plaintiffs' claims clearly forecast the issue they allege with Belviq's design – its impact on the serotonin pathway –

and allow the Court to "infer the existence of a design defect … rais[ing] a right to relief above the speculative level." *Hunter*, 505 F. Supp. 3d at 153 (cleaned up).

In sum, plausibility requires "enough fact[s] to raise a reasonable expectation that discovery will reveal evidence" of the alleged misconduct. *Twombly*, 550 U.S. at 556. Plaintiffs have met this standard with respect to their design defect claim.

**2. Failure to Warn and Negligence**

Plaintiffs' failure to warn claims arise under theories of negligence and strict liability.[4] Defendants do not seek dismissal of these claims to the extent that they are based on a duty to warn Dr. Kittler, Jennifer's prescribing physician. Rather, relying on the Learned Intermediary Doctrine, they seek dismissal only insofar as these claims allege defendants owed a duty to warn Jennifer directly, or for that matter anyone other than Dr. Kittler.

Under New York law, a pharmaceutical manufacturer has a duty "to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist." *DiBartolo*, 914 F. Supp. 2d at 611 (citing *Martin v. Hacker*, 607 N.Y.S.2d 598, 601 (N.Y. 1993)).

[4] "Failure to warn claims are identical under strict liability and negligence theories of recovery." *DiBartolo*, 914 F. Supp. 2d at 611 (citing *Lewis v. Abbott Labs.*, 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009)).

The New York Court of Appeals has adopted the "Informed Intermediary Doctrine," also known as the "Learned Intermediary Doctrine," which provides that a manufacturer's duty to warn "is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." *Martin*, 607 N.Y.S.2d at 601.

While the Court recognizes that the scope of a pharmaceutical manufacturer's duty to warn is governed by New York's Learned Intermediary Doctrine, defendants seem to be getting ahead of themselves. Indeed, defendants only seek to dismiss plaintiffs' claims insofar as they are based on an alleged failure to warn Jennifer personally, or anyone other than Dr. Kittler. Yet plaintiffs clearly allege that defendants failed to warn *both* Jennifer and Dr. Kittler, *see, e.g.*, Compl. ¶¶ 112-116, 123-125, and the claim would survive regardless of whether this Court granted defendants' requested relief. While defendants may feel that allegations concerning a failure to warn Jennifer directly are superfluous, such allegations do nothing to change the outcome of this motion. Defendants' argument may be more appropriate after discovery.

Accordingly, defendants' motion to dismiss plaintiffs' failure to warn claims arising under negligence and strict liability theories will be denied.

**B. Warranty Claims**

Defendants next move to dismiss plaintiffs' breach of warranty claims on the grounds that they are time-barred, that plaintiffs failed to allege pre-suit notice, and that the claims are insufficiently pleaded. The Court disagrees.

**1. Timeliness**

Ordinarily, breach of warranty claims have a four-year statute of limitations that "begins to run when the product is placed in the stream of commerce or at the time of sale by the manufacturer." *Baker v. Stryker Corp.*, 770 F. App'x 12, 15 (2d Cir. 2019).

However, on March 7, 2020, former Governor Andrew Cuomo issued Executive Order 202.8 (as well as nine subsequent executive orders), which affected the statutes of limitations for various claims, including those at issue here. *See* 9 NYCRR § 8.202.8. While there is some disagreement as to whether these executive orders "tolled" or "suspended" statutes of limitations, the plain language of Executive Order 202.8 states that statutes of limitations are "hereby tolled." Exec. Order No. 202.8 (March 7, 2020). This Court, as well as others in this Circuit, have determined that Executive Order 202.8 therefore operates as a toll, not a suspension. *See Johnston v. City of Syracuse,* 2021 WL 3930703, at *6 (N.D.N.Y. Sept. 2, 2021) ("It seems clear that New York's governor intended to toll – rather than suspend – the statute of limitations through his pandemic-related executive orders"); *Lopez-*

*Motherway v. City of Long Beach*, 2021 U.S. Dist. LEXIS 48597, at *20 (E.D.N.Y. Mar. 15, 2021) ("By using 'tolled,' Executive Order 202.8 says what it means and means what it says").[5]

Ordinarily, given that the latest sale of Belviq happened in August 2016, plaintiffs would have had until August 2020 to bring their breach of warranty claims. However, under Executive Order 202.8 and the executive orders following it, plaintiffs' warranty claims were tolled for approximately seven-and-a-half months, beginning on March 20, 2020, and ending on November 3, 2020. Plaintiffs thus had until March 2021, at the earliest, to bring their breach of warranty claims. Plaintiffs filed their complaint on February 8, 2021, making their claims timely.

**2. Pre-Suit Notice**

To recover on a warranty claim under the New York Uniform Commercial Code ("UCC"), a "buyer must within a reasonable time after he discovers or should have discovered any breach notify the seller of breach or be barred from any remedy." N.Y. U.C.C. § 2-607(3). The notice requirement is

[5] There is also some disagreement as to whether the governor had the power to toll the statute of limitations. *See Lopez-Motherway*, 2021 U.S. Dist. LEXIS 48597, at *21-22. The Court recognizes that this issue has yet to be "highly litigated" in New York state courts, though it notes several New York trial courts have considered the governor's authority to toll statutes of limitations and upheld that power. *See, e.g.*, *Bastell v. Vill. of Rye Brook*, 144 N.Y.S.3d 556 (Sup. Ct. Westchester Cty. 2021); *Chevra Gmilas Chesed Stropkover Joseph Chaim v. Washington Cemetery*, 148 N.Y.S.3d 370, 371 (Sup. Ct. Kings Cty. 2021)*; In re 701 River St. Assocs. LLC*, 148 N.Y.S.3d 365, 369 (Sup. Ct. Rensselaer Cty. 2021). While a New York appellate court may ultimately decide that the governor did not have power to toll the statute of limitations, it has not done so at this time.

"designed to defeat commercial bad faith, not to deprive a good faith consumer of his remedy." *Id.*, cmt. 4.

There is, however, an exception to the notice requirement where the product is for retail sale or where the product is intended for human consumption. *See Richards v. Johnson & Johnson, Inc.*, 2018 U.S. Dist. LEXIS 210184, at *5 (N.D.N.Y. Dec. 13, 2018); *Fischer v. Mead Johnson Labs.*, 341 N.Y.S.2d 257, 259 (Sup. Ct. App. Div. 3d Dep't 1973). Courts reason that requiring pre-suit notice for a complaint "grounded on tortious elements … on account of a defect of edible goods in a retail transaction would strain the rule beyond a breaking point of sense or proportion to its intended object." *See Richards*, 2018 U.S. Dist. LEXIS 210184, at *6 (citing *Fischer*, 341 N.Y.S.2d at 259); *see also Tomasino v. Estee Lauder Cos.*, 2015 U.S. Dist. LEXIS 103991, at *11 (E.D.N.Y. Aug. 7, 2015) ("regardless of the stated theory of recovery, there is no purpose in imposing a requirement relating to contracts on cases that essentially sound in tort law").

Defendants cite two cases suggesting that the above exception is a "minority view," but even those cases recognize that the exception applies to cases involving "products for human consumption," where a party alleges "physical injury." *See Bassaw v. United Indus. Corp.*, 482 F. Supp. 3d 80, 87 n.3 (S.D.N.Y. 2020); *Colella v. Atkins Nutritionals, Inc.*, 348 F. Supp. 3d 120, 143 (E.D.N.Y. 2018).

The other two cases defendants cite to cast doubt on the applicable exception are similarly unpersuasive. One, *Hunter*, did not involve a product for human consumption, but rather a heater. *See* 505 F. Supp. 3d at 158. The other, *Richards*, did dismiss plaintiff's breach of warranty claim for failure to allege pre-suit notice, but the plaintiff there cited "no case law to support the proposition that the notice requirement does not apply to 'goods intended for use in the human body.'" *Richards v. Johnson & Johnson, Inc*, 2018 WL 2976002, at *8 (N.D.N.Y. June 12, 2018). Nevertheless, the *Richards* court gave plaintiff leave to amend her claim, and specifically declined to dismiss it for lack of pre-suit notice when defendants again moved to dismiss the claim months later. *See Richards*, 2018 U.S. Dist. LEXIS 210184, at *7.

Plaintiffs' causes of action are for personal injury and involve a good sold for human consumption. The exception articulated in *Fischer* and the cases following it applies, and plaintiffs were not required to give pre-suit notice.

**3. Plaintiffs State a Claim for Breach of Implied Warranty**

To state a claim for breach of the implied warranty of merchantability, a plaintiff must show, as she would for strict products liability or negligence claims, that: (1) the product was defectively designed or manufactured; (2) the defect existed when the manufacturer delivered it to the purchaser or user; and (3) the defect was the proximate cause of the injury. *Scism*, 2020

WL 1245349, at *7. As with strict products liability or negligence claims, the defect may arise from "a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product." *DiBartolo*, 914 F. Supp. 2d at 627 (citing *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329, 345 (S.D.N.Y.2006)).

The thrust of defendants' argument for dismissal of plaintiffs' breach of implied warranty claim is that it fails because the design defect claim fails. However, as explained *supra*, plaintiffs stated sufficient facts for the Court to infer the existence of a design defect. Accordingly, defendants' argument is unpersuasive.

To the extent that defendants attack the sufficiency of plaintiffs' claim more broadly, the Court is likewise unpersuaded. As they did with plaintiffs' design defect claim, defendants cherry-pick but a few allegations and suggest that they do not support plaintiffs' implied warranty claim. In addition to alleging facts sufficient for the Court to infer that Belviq had a design defect (facts which plaintiffs incorporate into their implied warranty claim, Compl. ¶ 220), plaintiffs also allege, among other things, that defendants were responsible for all facets of Belviq's design, research, sale, and distribution, *id.* ¶ 221, and that Jennifer's injuries were caused from her use of Belviq, *id.* ¶¶ 245-47. This is sufficient to state a claim for breach of implied warranty, and plaintiffs' claim survives dismissal.

**4. Plaintiffs State a Claim for Breach of Express Warranty**

"Any 'affirmation of fact or promise made by a seller to a buyer which relates to the goods contemplated in a transaction and becomes part of the basis of a bargain creates an express warranty that the goods shall conform to the affirmation or promise.'" *Scism*, 2020 WL 1245349, at *7 (quoting N.Y. U.C.C. § 2-313(1)(a)). "A successful claim of a breach of express warranty requires proof that an express warranty existed, was breached, and that plaintiff had relied on that warranty." *Id*. (citing *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 578 (E.D.N.Y. 2012)). A plaintiff must plead the "exact terms of the warranty" as well as her reliance on those terms as a basis for the bargain. *O'Neil v. Argon Med. Devices, Inc.*, 2020 WL 1149904, at *7 (N.D.N.Y. Feb. 13, 2020).

Though they break it into two subparts, defendants simply argue that plaintiffs do not detail specific warranties that defendants made. The Court disagrees. Plaintiffs allege that defendants warranted and represented to Jennifer and Dr. Kittler that Belviq was safe and effective, and that the drug's safety outweighed any potential dangers and/or risks. *See, e.g.*, Compl. ¶¶ 178-79, 180. As to where defendants made these representations, plaintiffs point to television advertisements that Jennifer saw between 2015 and 2016, and the Belviq product label that both Jennifer and Dr. Kittler

reviewed and relied upon before Jennifer began taking the drug. *Id.* ¶¶ 181-84, 191-93, 194-96, 210.

Plaintiffs correctly note that statements about safety are not appropriately characterized as "merely general statements" about the quality of a product. *Williamson*, 2013 U.S. Dist. LEXIS 104445, at *24. This is especially true in the context of medical products. *Id.* Among other things, plaintiffs have adequately alleged the "where, when, and how" regarding defendants' statements, and thus state a claim for breach of express warranty.[6]

**C. Fraud-Based Claims**

Lastly, defendants seek to dismiss plaintiffs' fraudulent misrepresentation and concealment claims on the ground that they are not pleaded with particularity, as required by Rule 9(b) of the Federal Rules of Civil Procedure.

To maintain a fraud claim in New York, a plaintiff must allege that: "(1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiff thereby, (3) the plaintiff reasonably relied upon the misrepresentation, and (4) the plaintiff suffered damages as a result of such reliance." *Banque Arabe Et Internationale D'Investissement v.*

[6] Defendant Arena asks the Court to take judicial notice of certain FDA product labels purportedly showing that Arena never distributed nor sold Belviq in the United States, and argues that, for this reason, "there can be no basis as a matter of law for Plaintiffs' claims premised on any alleged express warranty by Arena." While defendant provides caselaw suggesting that the Court should take judicial notice of the product labels, it offers no authority explaining why the Court should dismiss the claims. Accordingly, the Court will reject defendant's argument.

*Maryland Nat'l Bank*, 57 F.3d 146, 153 (2d Cir. 1995) (citing *Keywell Corp. v. Weinstein*, 33 F.3d 159, 163 (2d Cir. 1994)). "A fraudulent concealment claim shares these same elements with the additional requirement that a plaintiff must show that the defendant had a duty to disclose the material information." *Zap v. Mortg. Elec. Registration Sys.*, 2016 U.S. Dist. LEXIS 150988, at *16 (N.D.N.Y. Nov. 1, 2016) (citing *Woods v. Maytag Co.*, 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)).

Moreover, a party alleging fraud "must state with particularity the circumstances constituting fraud ... " Fed. R. Civ. P. 9(b).[7] Pleading fraud with particularity means specifying the "who, what, when, where, and how [of the fraud]." *Papworth v. Steel Hector & Davis*, 2007 WL 2903944, at *8 (N.D.N.Y. Sept. 30, 2007)). To survive dismissal, claims must: "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, 375 F.3d 168, 187 (2d Cir. 2004).

Although Rule 9(b) allows "[m]alice, intent, knowledge, and other condition[s] of mind of a person [to] be averred generally," a plaintiff must

[7] This heightened pleading requirement applies to fraudulent misrepresentation claims as well as fraudulent concealment claims. *See Richards*, 2018 WL 2976002, at *7.

also "allege facts that give rise to a strong inference of fraudulent intent" when pleading fraud-based claims. *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006). "The requisite 'strong inference' of fraud may be established either: (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud; or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness" *Id*. at 290-91.

Defendants argue, among other things, that plaintiffs' vague allegations of fraudulent intent fail to satisfy Rule 9(b). The Court agrees. While plaintiffs allege that defendants made their purported fraudulent misrepresentations with the intent of defrauding consumers, prescribing physicians, and others so that physicians would recommend Belviq for weight management, Compl. ¶¶ 259-61, they plead no facts in support of these allegations. Without more, plaintiffs fail to show that defendants had motive and opportunity to commit fraud, or that there is strong circumstantial evidence of conscious misbehavior or recklessness. *See Lerner*, 459 F.3d at 290-91. Accordingly, plaintiffs fail to raise a strong inference of fraudulent intent, and thus fail to plead an element of both their fraudulent misrepresentation and concealment claims with particularity. Rule 9(b) dictates that these claims must be dismissed.

## V. CONCLUSION[8]

Therefore, it is

ORDERED that

1. Defendants' partial motions to dismiss are GRANTED in part and DENIED in part;

2. Plaintiffs' fifth cause of action (fraudulent misrepresentation and concealment) is DISMISSED;

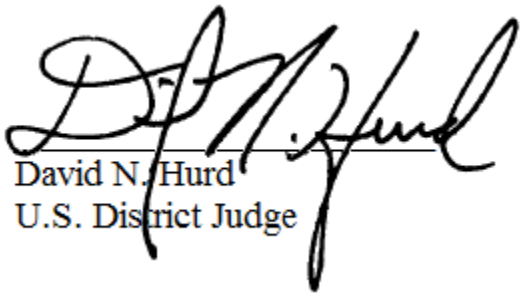
3. Plaintiffs' first cause of action (negligence), second cause of action (strict products liability – defective design and failure to warn), third cause of action (breach of express warranty), fourth cause of action (breach of implied warranty), and seventh cause of action (loss of consortium) remain;

4. Plaintiffs' request to amend the complaint is DENIED;

5. Defendants shall file an answer to the remaining claims on or before March 2, 2022.

[8] In their opposition to defendant Arena's motion to dismiss (Dkt. 21), plaintiffs include a brief paragraph requesting leave to amend their complaint. However, plaintiffs have not complied with the Local Rules of the Northern District of New York, which require a party moving to amend a pleading pursuant to Fed. R. Civ. P. 15 to attach an unsigned copy of the proposed amended pleading to its motion papers, to set forth specifically the proposed insertions and deletions of language, and to identify the amendments in the proposed pleading, either through a redline or other equivalent means. *See* L.R. 7.1(b)(4); L.R. 15.1(a). Accordingly, the Court denies plaintiffs' request.

IT IS SO ORDERED.



David N. Hurd
U.S. District Judge

Dated: February 16, 2022
Utica, New York.